UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Wave 8** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 8 CASES LISTED ON PLAINTIFFS' EXHIBIT A**	

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF DEBRA FROMER, M.D.

Plaintiffs challenge all of Dr. Fromer's warnings opinions, apparently misconstruing this Court's Wave 1 Order precluding Dr. Fromer's testimony on the *adequacy* of the IFU warnings to mean she can offer no warnings opinion at all. *See* Memorandum in Support of Pls.' Motion (Doc. No. 6900) at 3-4. Defendants acknowledge that this Court ruled that Dr. Fromer cannot "offer expert testimony about what information should or should not be included in an IFU," but the Order is restricted to that limitation on her warning opinions. *See In re Ethicon, Inc.*, Memorandum Opinion and Order (*Daubert* Motion re: Debra Fromer, M.D.), 2016 WL 4944331, *4 (S.D. W. Va. Aug. 31, 2016).[1] Accordingly, Dr. Fromer will not offer the opinion that the IFUs in issue "adequately" warned of potential complications or opine concerning what "should or should not be included in an IFU." That, however, does not preclude all of her opinions concerning the product warnings, as Plaintiffs suggest. Pls.' Mem. at 4. This Court also recognized in its Order concerning Dr. Fromer that physicians "may testify about the

[1] Defendants adopt and incorporate by reference their Response to Plaintiffs' Motion to Exclude Debra Fromer, M.D., in Wave 1, Doc. No. 2151.

specific risks of implanting mesh and whether those risks appeared in the relevant IFU." *In re Ethicon*, 2016 WL 4944331, *4. As a result, Plaintiffs' Motion should be denied.

BACKGROUND

Dr. Fromer is Chief of Female Pelvic Medicine and Reconstructive Surgery at Hackensack University Medical Center. *See* Ex. B to Pls.' Mot., Fromer Report (7/30/18) at 1. She is board Certified in Female Pelvic Medicine and Reconstructive Surgery. *Id*. at 2. Her practice largely consists of treating women for "urinary incontinence, prolapse, recurrent urinary tract infection, female sexual dysfunction, and pelvic pain." *Id*. at 2. She has performed over 500 surgical procedures for pelvic organ prolapse, most of which involved a polypropylene graft, and more than 150 of which involved some kind of Prolift. *Id*. She is actively involved in training urology residents and subspecialty fellows in Female Pelvic Medicine and Reconstructive Surgery. *Id*. at 3-4. She also served as a preceptor for Ethicon, training residents, fellows and attending surgeons on the use of Prolift and other mesh devices. *Id*. at 4. Her Report is replete with references to peer-reviewed medical literature and studies.

Plaintiffs do not challenge Dr. Fromer's overall qualifications. Instead, they argue that she is precluded from offering any warning opinion at all, relying on this Court's Wave 1, limited exclusion of her warning opinions related only to opinions concerning the adequacy of IFU warnings. Pls.' Mem. at 4. They also challenge the results of a survey that is the subject of a 2018 published article written by Dr. Fromer, arguing that Dr. Fromer's conclusion that physicians rely "more heavily on other information such as intensive training, a robust body of medical literature, and medical conferences, rather than the IFU, in planning, consent process and surgical technique" is unsupported. Pls.' Mem. at 5. Any such disagreement with Dr.

Fromer's conclusions is fodder for cross examination, and not appropriate grounds to exclude her opinions.

ARGUMENT

I. Dr. Fromer is qualified to offer warnings opinions that do not run afoul of this Court's prior ruling concerning her opinions.

According to the FDA regulations governing warnings, a product IFU need not warn of risks that are known generally to the users of products. The FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are **commonly known to practitioners licensed by law to use the device**.

21 C.F.R. §801.10(c) (emphasis added); *see also Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). That makes sense, for otherwise product warnings would be so voluminous as to defy any worth.

Because of this legal standard, Ethicon is entitled to defend the adequacy and contents of its warnings by referencing what licensed surgeons would know about the risks associated with pelvic floor surgery, including surgery using mesh augmentation. That necessarily includes information that a surgeon would learn through education, clinical training and professional development. Since Ethicon's warnings are not to be judged by just what one particular surgeon knew, but by what commonly would be known to such physicians generally, Ethicon's experts can reference the common knowledge of surgeons in offering opinions concerning Ethicon's warnings. *Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006) ("expert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts."); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*,

348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant).

As noted by this Court, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec.16, 2011)). Based upon this, it is wholly appropriate for Dr. Fromer to opine regarding which risks exist (or do not exist) associated with the Prolift and whether these risks were identified in the IFU or were otherwise generally known to pelvic floor surgeons.

Dr. Fromer is qualified to and equipped to offer such opinions. She relied on her extensive training, education, experience, and review of medical and scientific literature as identified and set forth in her Report. *See* Ex. B to Pls.' Mot., Fromer (7/30/18) Report; *see also* Defendants' Response in Opposition to Plaintiffs' Motion to Exclude Dr. Fromer, Doc. No. 2151, at 3. Dr. Fromer specializes in disorders of the female pelvic floor and has conducted approximately 500 surgical procedures to address pelvic organ prolapse, over 150 of which involved the Prolift system. Ex. B to Pls.' Mot., Fromer Report at 2-3. Her Report is clear that her opinions are based on the knowledge and experience obtained in her clinical practice as well as on peer-reviewed studies and randomized controlled trials. *Id*. She also assisted and trained other surgeons on the use of Prolift. *Id*. at 5.

This Court has allowed opinions on a product's safety and efficacy that draw upon a physician's clinical experience and review of relevant literature. *See Tyree v. Boston Scientific*

Corp., 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). A physician is also qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Winebarger*, 2015 WL 1887222, at *15 (finding expert qualified to give opinions on product labeling based on his clinical experience). Dr. Fromer does just that and is qualified to do so. Plaintiffs' Motion to exclude all of her warning opinions should be denied.

II. Plaintiffs' challenge to recent reliance materials of Dr. Fromer's goes to weight and not to admissibility.

Plaintiffs assert that "Dr. Fromer should be prohibited from rendering opinions based on her recent survey that are not actually supported by the study's results." Pls.' Mem. at 4. Plaintiffs' argument is based on mere disagreement with Dr. Fromer's opinion that implanting physicians rely ""more heavily on other information such as intensive training, a robust body of medical literature, and medical conferences, rather than the IFU, in planning, consent process and surgical technique." Pls.' Mem. at 5.

Plaintiffs suggest that since the survey on which Dr. Fromer reported showed that certain percentages of physicians read the IFU "at least once," then Dr. Fromer's conclusion is erroneous. The fact is that the study reported the actual numbers associated with the survey responses, and Plaintiffs are free to cross examine Dr. Fromer about their perceived lack of support for her conclusion. That Plaintiffs believe reading an IFU one time means that it is crucial information to surgeons while Dr. Fromer concludes that a single reading of an IFU over the span of a surgeon's practice does not elevate it to that level is appropriate for cross examination. Plaintiffs' disagreement with Dr. Fromer does not constitute grounds to exclude this opinion and study. *See* Mem. Op. and Order re Dr. Fromer, Doc. 2702, at 4 (interest in

accuracy counsels in favor of reserving issues for trial); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *11 (S.D.W. Va. Feb. 7, 2015) ("listening to testimony and deciding whether it is contradictory is the quintessential jury function of determining credibility of witnesses."). It is not within the parameters of *Daubert* for this Court to determine the correctness of Dr. Fromer's testimony, as such weighing is within the province of the jury. *Harris v. Norfolk Southern Ry. Co.*, 2013 WL 1136644, *3 (S.D. W. Va. March 18, 2013) (on *Daubert* challenge, court "need not determine that the proffered expert testimony is irrefutable or certainly correct—as with all other admissible evidence, expert testimony is subject to testing by vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.") (internal quotations and citations omitted).

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs' motion to exclude the opinions and testimony of Dr. Fromer beyond the limitation placed on her warning opinions in this Court's Wave 1 order concerning the IFU adequacy.

Respectfully submitted,

/s/ *William M. Gage*
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ *Susan M. Robinson*
Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)

P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

COUNSEL FOR DEFENDANTS

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage